

## General

### Guideline Title

Benefits and risks of sterilization.

### Bibliographic Source(s)

American College of Obstetricians and Gynecologists (ACOG). Benefits and risks of sterilization. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2013 Feb. 13 p. (ACOG practice bulletin; no. 133). [107 references]

### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Benefits and risks of sterilization. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2003 Sep. 12 p. (ACOG practice bulletin; no. 46). [104 references]

## Recommendations

### Major Recommendations

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of the "Major Recommendations" field.

The following recommendations and conclusions are based on good and consistent scientific evidence (Level A):

- Tubal occlusion by laparoscopy is a safe and effective method of permanent contraception.
- Tubal occlusion does not protect against sexually transmitted infections (including human immunodeficiency virus [HIV]).
- Compared with abdominal approaches to female sterilization, vasectomy is safer, more effective, and less expensive.
- Laparoscopic tubal occlusion is far more effective than short-term, user-dependent, reversible contraceptive methods, such as oral contraceptive pills, injections, and barrier methods.
- Long-acting methods of contraception, including intrauterine devices (IUDs) and the contraceptive implant, are at least as effective as tubal occlusion and are associated with lower morbidity and mortality.
- Although pregnancy after a sterilization procedure is uncommon, there is substantial risk that any post-sterilization pregnancy will be ectopic.
- Patients who have undergone sterilization procedures have a lower ectopic risk than noncontraceptive users.

The following recommendations and conclusions are based on limited or inconsistent scientific evidence (Level B):

- Hysteroscopic occlusion techniques, followed by a confirmatory hysterosalpingography (HSG), have at least equal if not superior efficacy to tubal occlusion done via laparoscopy or minilaparotomy.
- Hysteroscopic procedures require the use of an alternative method of contraception for at least 3 months after the procedure and until a

confirmatory HSG indicates successful tubal occlusion.

- Postpartum partial salpingectomy is associated with lower failure rates than interval tubal occlusions done via laparoscopy.
- Laparoscopic tubal occlusion reduces the incidence of ovarian cancer.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Women should be counseled about the risk of failure, risk of regret, and alternatives (including long-acting reversible contraception [LARC] and vasectomy). In a well-informed woman, age and parity should not be a barrier to sterilization.

#### Definitions:

##### Grades of Evidence

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

##### Levels of Recommendations

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

## Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

Unintended pregnancy

### Guideline Category

Assessment of Therapeutic Effectiveness

Counseling

Prevention

Risk Assessment

### Clinical Specialty

Obstetrics and Gynecology

Surgery

## Intended Users

Physicians

## Guideline Objective(s)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review the evidence for the safety and effectiveness of female sterilization in comparison with male sterilization and other forms of contraception

## Target Population

Women and men of reproductive age

## Interventions and Practices Considered

### Female Sterilization

1. Timing of tubal sterilization procedure (postpartum, postabortion, interval)
2. Patient and partner presterilization counseling
3. Sterilization approaches and techniques:
  - Hysteroscopy
  - Laparoscopy
  - Electrocoagulation
  - Mechanical devices (e.g., Essure insert)
  - Tubal excision (i.e., salpingectomy)
  - Minilaparotomy, including Pomeroy and Parkland methods

### Male Sterilization

1. Vasectomy
2. Semen analysis to confirm azoospermia

## Major Outcomes Considered

- Minor and major complications of sterilizations procedures, including mortality
- Failure rate
- Ovarian cancer incidence
- Rate of subsequent hysterectomy
- Probability of regret

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

## Description of Methods Used to Collect/Select the Evidence

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1990–October 2012. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician–gynecologists were used.

## Number of Source Documents

Not stated

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

## Description of the Methods Used to Analyze the Evidence

Not stated

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from

obstetrician–gynecologists were used. See the "Rating Scheme for the Strength of the Recommendations" field regarding Level C recommendations.

## Rating Scheme for the Strength of the Recommendations

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

Internal Peer Review

## Description of Method of Guideline Validation

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Safe and effective use of sterilization procedures for women and men

### Potential Harms

Women

- Tubal occlusion via *laparoscopy* has a low overall complication rate, and procedure-related death is a rare event. This complication rate did not vary significantly according to the method of occlusion used. Intraoperative complications include unplanned major surgery needed because of a problem related to the tubal surgery, transfusion, or a life-threatening event. Postoperative complications include unintended major surgery, transfusion, febrile morbidity, a life-threatening event, or rehospitalization. Use of general anesthesia, previous abdominal or pelvic surgery, obesity, and diabetes were independent predictors of complication.
- The disadvantages of *laparoscopy* include the risk of bowel, bladder, or major vessel injury.

- Monopolar *electrocoagulation* is associated with thermal bowel injury.
- *Mechanical devices* are most likely to be effective when used to occlude a normal fallopian tube; tubal adhesions, thickened tubes, or dilated fallopian tubes may increase the risk of misapplication and subsequent failure. Spontaneous clip migration or expulsion is rare.
- For *all methods of sterilization* except postpartum partial salpingectomy, the probability of ectopic pregnancy was greater for women sterilized before age 30 years than for women sterilized at age 30 years or older.
- There is some concern that *salpingectomy* may adversely affect ovarian function.
- Although there are certain key indicators for future *regret*—such as young age (less than age 30) at the time of sterilization—many indicators of regret are part of individual social circumstances, which should be explored with the patient before a decision is made.

## Men

- Minor complications of *vasectomy* include infection at the site of incision, bleeding, hematoma formation, granuloma formation, and epididymitis. Vasectomy-related major morbidity and mortality are extremely rare in the United States.
- Chronic testicular pain may rarely result from obstructive epididymitis or sperm granuloma.

## Contraindications

### Contraindications

- Hysteroscopic techniques are not indicated for sterilization after delivery or abortion.
- Minilaparotomy generally is reserved for postpartum procedures and rarely considered for patients at high risk of complications associated with laparoscopic procedures.

Note: In 2011, the nickel sensitivity contraindication was removed from the Essure procedure instructions. Patients with nickel sensitivity are candidates for Essure and do not require preprocedure confirmatory skin testing. However, they should be counseled that microinserts do contain minute amounts of nickel, which are likely to be of no clinical significance.

## Qualifying Statements

### Qualifying Statements

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.

### Implementation Tools

Foreign Language Translations

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Staying Healthy

## IOM Domain

Effectiveness

Patient-centeredness

Safety

## Identifying Information and Availability

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### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2003 Sep (revised 2013 Feb)

### Guideline Developer(s)

American College of Obstetricians and Gynecologists - Medical Specialty Society

### Source(s) of Funding

American College of Obstetricians and Gynecologists (ACOG)

### Guideline Committee

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

### Composition of Group That Authored the Guideline

American College of Obstetricians and Gynecologists (ACOG) committees are created or abolished and their overall function defined by the Executive Board. Appointments are made for one year, with the understanding that such appointment may be continued for a total of three years. The majority of committee members are Fellows, but Junior Fellows also are eligible for appointment. Some committees may have representatives from other organizations when this is particularly appropriate to committee activities. The president elect appoints committee members annually.

### Financial Disclosures/Conflicts of Interest

Not stated

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## Guideline Availability

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 933104, Atlanta, GA 31193-3104; telephone, 800-762-2264, ext. 192; e-mail: [sales@acog.org](mailto:sales@acog.org). The ACOG Bookstore is available online at the [ACOG Web site](#) .

## Availability of Companion Documents

None available

## Patient Resources

The following are available:

- Frequently asked questions: Sterilization for women and men. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2013 Aug. 3 p. Electronic copies: Available in Portable Document Format (PDF) from the [American College of Obstetricians and Gynecologists \(ACOG\) Web site](#).  Copies are also available in [Spanish](#) .
- Frequently asked questions: Sterilization by laparoscopy. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2012 May. 3 p. Electronic copies: Available in PDF from the [ACOG Web site](#) . Copies are also available in [Spanish](#) .
- Frequently asked questions: Hysteroscopic sterilization. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2013 Jan. 3 p. Electronic copies: Available from the [ACOG Web site](#) . Copies are also available in [Spanish](#) .
- Frequently asked questions: Postpartum sterilization. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2011 Aug. 2 p. Electronic copies: Available from the [ACOG Web site](#) . Copies are also available in [Spanish](#) .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## NGC Status

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